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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|----------------------------------|-------------|-----------------------|---------------------|------------------|--|
| 10/019,643 | 03/20/2002 | Richard Fayrer-Hosken | 235.00300101 | 1109 | |
| 26813 | 7590 | EXAMINER | | | |
| MUETING, RAASCH & GEBHARDT, P.A. | | | | NOLAN, PATRICK J | |
| P.O. BOX 581415 | | | ART UNIT | PAPER NUMBER | |
| MINNEAPOLIS, MN 55458 | | | 1644 | | |

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/019,643 | FAYRER-HOSKEN ET AL. | |
| | Examiner | Art Unit | |
| | Patrick J. Nolan | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 January 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4,6,12-21,23 and 27-29 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4,6,12-21,23 and 27-29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

1. Claims 4, 6, 12-21, 23 and 27-29 are pending.
2. All previous rejections have been overcome, a new ground of rejection and a Non-final office action is set forth below.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 4, 6, 12-21, 23 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a reproductive disease that is related to egg laying or fertilization, does not reasonably provide enablement for treating neoplasia of the reproductive tract or cystic hyperplasia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

It is well established that the cause of cancers is uncontrolled cell growth that escapes immune system regulation, see Kuby et al. (enclosed). Applicant's invention is drawn to administering a zona pellucida protein to help treat fertility and reproductive associated with egg laying in birds. The administration of said zona pellucida protein, elicits antibodies against the zona pellucida present on ova in the hens. When the antibodies bind to the zona pellucida proteins they sterically hinder the ability of sperm from male chickens to fertilize the hen ova. It is reasonable to control fertility in these hens with such a treatment. However the ability to treat or prevent cancers in these Hens has no sound scientific basis. The specification provides no link between fertility and cancer, and it has not been recognized by science that preventing fertility would help treat cancers of the reproductive tract or cystic hyperplasia. In light of the lack of working examples or guidance as to how to practice the claimed invention to treat cancers by inhibiting fertilization, it would be unpredictable and require an undue amount of experimentation in light of the state of cancer, to practice the full scope of applicant's claimed invention.

5. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.



Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

5/3/2004